

PATENT COOPERATION TREATY

COPY TO ATTY
W/OUT FILE

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

BRINKS HOFER GILSON & LIONE
Attn. Le Duc, Timothy J.
P.O. Box 10087
Chicago, IL 60610
UNITED STATES OF AMERICABRINKS HOFER
RECEIVED
SEP 27 2005
RECEIVED
GILSON & LIONENOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 8627-804	Date of mailing (day/month/year) 21/09/2005
International application No. PCT/US2005/010037	FOR FURTHER ACTION See paragraphs 1 and 4 below International filing date (day/month/year) 24/03/2005
Applicant COOK INCORPORATED	

BEST AVAILABLE COPY

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.**Where?** Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until **30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Sylvie Fernandez

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 8627-804	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2005/010037	International filing date (day/month/year) 24/03/2005	(Earliest) Priority Date (day/month/year) 26/03/2004
Applicant COOK INCORPORATED		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 6 sheets.



It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.



The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐ Certain claims were found unsearchable (See Box II).

3. ☒ Unity of invention is lacking (see Box III).

4. With regard to the title,

the text is approved as submitted by the applicant.



the text has been established by this Authority to read as follows:

5. With regard to the abstract,

the text is approved as submitted by the applicant.



the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. 1



as suggested by the applicant.



as selected by this Authority, because the applicant failed to suggest a figure.



as selected by this Authority, because this figure better characterizes the invention.

- b. ☐ none of the figures is to be published with the abstract.

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M39/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M F16L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/147429 A1 (COWAN KEVIN P ET AL) 10 October 2002 (2002-10-10) paragraph '0118! - paragraph '0122!; figures 4,5	1,3,5,6
X	WO 03/020361 A (CLINICAL PRODUCT DEVELOPMENT LIMITED; PETERS, JOSEPH, LENNOX; WATKINSO) 13 March 2003 (2003-03-13) page 7, line 1 - page 8, line 4; figures 1-7	5-7
A		2,17
X	GB 735 202 A (SURDENT MANUFACTURING COMPANY LIMITED) 17 August 1955 (1955-08-17) page 2, line 22 - line 33; figures 1-5	5,8
	----- -/--	

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.*** Special categories of cited documents:**

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

* & * document member of the same patent family

Date of the actual completion of the international search

7 September 2005

Date of mailing of the international search report

21 SEP 2005

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Schönleben, J

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2005/010037

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 747 632 A (KOK A,CH ET AL) 24 July 1973 (1973-07-24) column 3, line 5 - line 60; figures 1,2	5
A	-----	3,8,18
A	US 6 565 550 B1 (KLEIN DEAN A ET AL) 20 May 2003 (2003-05-20) column 3, line 60 - line 63; figures 1,2	4,5,9,19
A	-----	1
	US 5 919 169 A (GRAMS ET AL) 6 July 1999 (1999-07-06) column 2, line 66 - column 3, line 17; figure 1	
X	-----	
	US 6 332 633 B1 (FITOUSSI GILLES ET AL) 25 December 2001 (2001-12-25) column 3, line 1 - column 4, line 36; figures 1-3	11-16,20
X	-----	
	US 5 830 195 A (PETERS ET AL) 3 November 1998 (1998-11-03) column 3, line 53 - column 4, line 5; figure 1	11-16,20
X	-----	
	US 5 651 776 A (APPLING ET AL) 29 July 1997 (1997-07-29) column 3, line 15 - line 56; figures 1,2	11-13
A	-----	17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/010037

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-10

A luer fitting connector assembly comprising a locking member and a male or female luer fitting member whereby the locking member has a skeletal handle, a finlike handle, a cavity grip, or an undulating grip

2. claims: 11-13,14-20

A luer fitting connector assembly comprising a locking member and female or male luer fitting member whereby the luer fitting member has a conical restraining surface comprising a rim and the locking member has an annular inwardly protruding plateau shaped protrusion.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2005/010037

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 2002147429	A1	10-10-2002	WO 02066100 A2	29-08-2002
WO 03020361	A	13-03-2003	GB 2379253 A	05-03-2003
			EP 1432468 A2	30-06-2004
			WO 03020361 A2	13-03-2003
			GB 2410305 A	27-07-2005
			JP 2005501616 T	20-01-2005
			US 2004238776 A1	02-12-2004
GB 735202	A	17-08-1955	NONE	
US 3747632	A	24-07-1973	CH 522844 A	15-05-1972
			CH 537552 A	31-05-1973
			DE 2112210 A1	04-11-1971
			FR 2084606 A5	17-12-1971
			GB 1324906 A	25-07-1973
US 6565550	B1	20-05-2003	CA 2369317 A1	16-11-2000
			EP 1183063 A1	06-03-2002
			JP 2002543894 T	24-12-2002
			WO 0067833 A1	16-11-2000
US 5919169	A	06-07-1999	NONE	
US 6332633	B1	25-12-2001	NONE	
US 5830195	A	03-11-1998	DE 69518740 D1	12-10-2000
			DE 69518740 T2	31-05-2001
			EP 0998956 A2	10-05-2000
			EP 0743868 A1	27-11-1996
			ES 2153023 T3	16-02-2001
			WO 9522369 A1	24-08-1995
			JP 9508840 T	09-09-1997
			US 6217564 B1	17-04-2001
US 5651776	A	29-07-1997	AT 180686 T	15-06-1999
			AU 691732 B2	21-05-1998
			AU 4824396 A	03-10-1996
			CA 2172001 A1	23-09-1996
			DE 69602658 D1	08-07-1999
			DE 69602658 T2	02-12-1999
			EP 0733380 A1	25-09-1996
			ES 2135125 T3	16-10-1999
			IL 117570 A	29-06-2000
			JP 8317994 A	03-12-1996

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2005/010037

International filing date (day/month/year)
24.03.2005

Priority date (day/month/year)
26.03.2004

International Patent Classification (IPC) or both national classification and IPC
A61M39/10

Applicant
COOK INCORPORATED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of ~~22 months from the priority date~~ whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office - P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040 Tx: 31 651 epo nl
Fax: +31 70 340 - 3016

Authorized Officer

Schönleben, J

Telephone No. +31 70 340-2436



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

10/594181
IAP16 Rec'd PCT/PTO 25 SEP 2006
International application No.
PCT/US2005/010037

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2005/010037

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☒ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 i
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
 - ☐ the parts relating to claims Nos.

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	2,4,7-10,17-19
	No: Claims	1,3,5,6,11-16,20
Inventive step (IS)	Yes: Claims	
	No: Claims	1-20
Industrial applicability (IA)	Yes: Claims	1-20
	No: Claims	

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2005/010037

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

**WRITTEN OPINION OF THE
 INTERNATIONAL SEARCHING
 AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2005/010037

Re Item IV.

The application as claimed in claims 1 to 20 refers to two different subject-matters and therefore fails to meet the requirements of Rule 13.1 PCT.

The different subject-matters referred to in the application are:

I. Claims 1-4, and 5-10: A luer fitting connector assembly comprising a locking member and a male or female luer fitting member whereby the locking member has a skeletal handle, a finlike handle, a cavity grip, or an undulating grip.

II. Claims 11-13 and 14-20: A luer fitting connector assembly comprising a locking member and female or male luer fitting member whereby the luer fitting member has a conical restraining surface comprising a rim and the locking member has an annular inwardly protruding plateau shaped protrusion.

These two subject-matters defined by the above two groups of claims are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

The features common to all claims are: A luer fitting connector assembly comprising a locking member and a female or male luer fitting member. However, such a luer fitting connector is generally known so that the features common to all claims cannot be special technical features in the meaning of Rule 13.2 PCT.

The remaining features of independent claims 1, 5 on the one hand and of independent claims 11 and 14 on the other hand are different and have different purposes (enhanced handling and control of the luer fitting, preventing inadvertent separation of the locking member, respectively) and, therefore, are neither the same nor corresponding features within the meaning of Rule 13.2 PCT so that the technical relationship between the different groups is lacking.

As such, without a technical relationship the subject-matters are not so linked as to form a single general inventive concept required by Rule 13.1 PCT.

Re Item V.

- 1 Reference is made to the following documents:
- D1: US 2002/147429 A1 (COWAN KEVIN P ET AL) 10 October 2002 (2002-10-10)
 - D2: WO 03/020361 A (CLINICAL PRODUCT DEVELOPMENT LIMITED; PETERS, JOSEPH, LENNOX; WATKINSO) 13 March 2003 (2003-03-13)
 - D3: GB 735 202 A (SURDENT MANUFACTURING COMPANY LIMITED) 17 August 1955 (1955-08-17)
 - D4: US-A-3 747 632 (KOK A,CH ET AL) 24 July 1973 (1973-07-24)
 - D5: US-B1-6 565 550 (KLEIN DEAN A ET AL) 20 May 2003 (2003-05-20)
 - D6: US-A-5 919 169 (GRAMS ET AL) 6 July 1999 (1999-07-06)
 - D7: US-B1-6 332 633 (FITOUSSI GILLES ET AL) 25 December 2001 (2001-12-25)
 - D8: US-A-5 830 195 (PETERS ET AL) 3 November 1998 (1998-11-03)
 - D9: US-A-5 651 776 (APPLING ET AL) 29 July 1997 (1997-07-29)

2 INDEPENDENT CLAIM 1

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.
- 2.2 Document D1 discloses (see paragraphs 0118 to 0122, and fig. 4,5; the references in parentheses applying to this document) a luer fitting connector assembly operable to interconnect a male luer fitting member and a female luer fitting member, the luer fitting connector assembly comprising one of the male or female luer fitting members 720, and a locking member 740 mounted upon said one of the female or male luer fitting members 720, the locking member 740 comprising a cavity grip, having an indentation approximating the shape of a human thumbprint (see D1, fig. 4D, the indentations before forward ends 744a, 744b).

As such, Document D1 discloses in combination all the features of present claim 1, so that the subject-matter of claim 1 is not new.

3 INDEPENDENT CLAIM 5

- 3.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 5 is not new in the sense of Article 33(2) PCT.
- 3.2 Independent claim 5 differs from claim 1 only in that the locking member comprises at least one of a skeletal handle, an undulating grip, and a finlike handle. If a finlike handle is present then the finlike handle extends a majority of the length of the locking member.

Document D1, however, discloses at least one of the alternatives mentioned in claim 5: According to fig. 5D the locking member comprises an undulating grip. As such, Document D1 also discloses in combination all the features of one alternative specified in present claim 5, so that the subject-matter of claim 5 is not new.

4 DEPENDENT CLAIMS 2-4, 6-10

Dependent claims 2-4 and 6-10 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT). See documents D1-D5 and the passages cited in the search report. As far as some of the dependent claims are not covered by these documents these dependent claims just define constructional details which come within the scope of the customary practice followed by persons skilled in the art.

5 INDEPENDENT CLAIM 11

- 5.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.
- 5.2 Document D9 discloses (see col. 3, lines 18 to 56 and fig. 1, 2; the reference in parentheses applying to this document) a luer fitting connector assembly operable to interconnect a male luer fitting member and a female luer fitting member, the luer fitting connector assembly comprising one of the male (14) or female (12) luer fitting members, said male luer fitting member (14) comprising a conical restraining surface (18), the conical restraining surface comprising a rim approximately orthogonal to the longitudinal axis of the said male luer fitting member, and a locking member (16) comprising a hollow central lumen, an

**WRITTEN OPINION OF THE
 INTERNATIONAL SEARCHING
 AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2005/010037

annular, inwardly protruding plateau (22) shaped protrusion, and a body that extends axially beyond at least a portion of the conical restraining surface and toward a proximal end of said male luer fitting member when the locking member is mounted upon said male luer fitting member.

As such, Document D9 discloses in combination all the features of present claim 1, so that the subject-matter of claim 1 is not new.

6 INDEPENDENT CLAIM 14

- 6.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 14 does not involve an inventive step in the sense of Article 33(3) PCT.
- 6.2 Document D7 discloses (see col. 3, line 1 to col. 4, line 36, and fig. 1 to 3; the reference in parentheses applying to this document) a method of assembling a luer fitting connector assembly comprising a male luer fitting member and a female luer fitting member, the method comprising: providing one of the male (12) or female (14) luer fitting members comprising a conical restraining surface (34), the conical restraining surface comprising a rim, providing a locking member (54) comprising a hollow central lumen, an annular, inwardly protruding plateau shaped protrusion (30), and a body that extends axially beyond at least a portion of the conical restraining surface and toward a proximal end of said male luer fitting member when the locking member is mounted upon said male luer fitting member, and mounting the locking member upon said male luer fitting member from the rear of said male luer fitting member, whereby the luer fitting connector assembly is assembled.

The subject-matter of claim 14 differs from this prior art only in that the rim of the restraining surface is approximately orthogonal to the longitudinal axis of the male luer fitting member. However, whether the rim is orthogonal to the axis of the male luer fitting member or not does not at all influence the method of assembling the locking member onto the male luer fitting member from the rear. As such, this difference cannot be considered as involving an inventive step (Article 33(3) PCT).

7 DEPENDENT CLAIMS 12, 13, 15-20

Dependent claims 12, 13 and 15-20 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT). See documents D2, D4, D5 and D7-D9 and the passages cited in the search report.

Re Item VII.

Independent claims 1, 5, 11 and 14 are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1, D2) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1, D2 and D7, D9, respectively, is not mentioned in the description, nor are these documents identified therein.

Re Item VIII.

- 1 Although claims 1 and 5 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.
- 2.1 It is clear from the description in paragraphs 31 and 54 that the following feature is essential to the definition of the invention: The male or female luer fitting members comprise apart from the conical restraining surface a distal tubular surface, against which the plateau shaped protrusion of the locking member would rest after assembly from the rear of the luer fitting member.
- 2.3 Since independent claims 11 and 14 do not contain this feature they do not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3(b) PCT that any independent claim must contain all the technical features essential

to the definition of the invention.

- 3 Throughout the description at least some of the features specified in the independent claims are disclosed as being optional (e.g. "the fitting member *may* include..."). This inconsistency between the claims and the description leads to doubt concerning the matter for which protection is sought, thereby rendering the claims unclear, Article 6 PCT.